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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,020	09/29/2000	Thomas J. Gardella	0609.4820002/SRL/TBB	2982

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/672,020	<b>Applicant(s)</b> GARDELLA ET AL.	
	<b>Examiner</b> Joseph F Murphy	<b>Art Unit</b> 1646	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 17 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,3,8,10-12 and 42.


Claim(s) withdrawn from consideration: 4-7 and 13-41.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_



Continuation of 5. does NOT place the application in condition for allowance because: The reply does not overcome the rejection under 35 USC ' 112 first paragraph as lacking enablement. Claim 1 has been amended to add the limitation wherein the polypeptide has a "biological activity substantially similar to the biological activity of parathyroid hormone". Applicant argues that the Specification has provided ample guidance as to structural features that enable a mutein or fragment to maintain activity, and that the addition of the functional limitation obviated the rejection. However, the claim as now written recites that the encoded polypeptide must have a biological activity substantially similar to the biological activity of parathyroid hormone, but does not indicate what that function must be. The term "biological activity substantially similar to the biological activity of parathyroid hormone" is not clear and the skilled artisan would not be apprised of the metes and bounds of the functional limitation with regard to the function of the encoded polypeptide. For instance, various biological activities can be attributed to an encoded polypeptide. For example, "activity" could constitute transportation throughout a cell, alteration of tertiary structure due to changes in pH, ligand binding, or modulation of second messenger effect, etc. 'Activity' could also be referring to the ability of the encoded polypeptide to stimulate antibody production. Since detailed information regarding the structural and functional requirements of the encoded polypeptide is lacking, it is thus unpredictable as to which variations, if any, meet the limitations of the claims.

Additionally, the reply does not overcome the rejection under 35 USC ' 112 first paragraph as lacking written description. Claim 1 has been amended to add the limitation wherein the polypeptide has a biological activity substantially similar to the biological activity of parathyroid hormone. Applicant argues that the results set forth in the Specification constitute a sufficient description of a representative number of species and satisfies the written description requirement. However, the claim as now written recites that the encoded polypeptide must have a biological activity substantially similar to the biological activity of parathyroid hormone, but does not indicate what that function must be. The term "biological activity substantially similar to the biological activity of parathyroid hormone" is not clear and the skilled artisan would not be apprised of the metes and bounds of the functional limitation with regard to the function of the encoded polypeptide. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the genus of encoded polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from other seven transmembrane region compounds are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed: there is no guidance in the art as to what the defining characteristics of the polypeptides might be. Thus, no identifying characteristics or properties of the instant polynucleotides encoding polypeptides are provided such that one of skill would be able to predictably identify the molecules that would retain "biological activity substantially similar to the biological activity of parathyroid hormone" of the polypeptides..

  
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